Louisiana Medicaid
Zoledronic Acid (Reclast®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for zoledronic acid (Reclast®).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- Zoledronic acid (Reclast®) has been prescribed for **ONE** of the following conditions / diagnoses:
    - Treatment or prevention of postmenopausal osteoporosis; **OR**
    - Treatment or prevention of glucocorticoid-induced osteoporosis [Prevention is indicated in recipients who require chronic use of systemic glucocorticoids and who are expected to remain on glucocorticoids for at least 12 months [Drug, dosage, diagnosis associated with long-term use of glucocorticoids, and anticipated duration of treatment must be stated on the request]; **OR**
    - Treatment of osteoporosis in men; **OR**
    - Treatment of Paget's disease; **AND**
- The recipient has a history of failure, contraindication, or intolerance to at least one preferred *Bone Resorption Suppressive Agents* indicated for the diagnosis for which zoledronic acid (Reclast®) was prescribed (drug names, dates of usage, and other details are **documented on request**); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of zoledronic acid (Reclast®); **AND**
    - The recipient will not receive zoledronic acid (Reclast®) in combination with any medication that is contraindicated or not recommended per FDA labeling; **AND**
    - Women of childbearing age have had a negative pregnancy test within 30 days prior to therapy initiation and have been educated regarding the dangers of becoming pregnant while taking zoledronic acid (Reclast®).

Reauthorization Criteria*

- The recipient continues to meet initial approval criteria; **AND**
- The recipient has had a positive response to treatment with zoledronic acid (Reclast®) as indicated by an improvement in BMD when compared to baseline; **AND**

- The recipient has been reassessed for fracture risk and continuation of treatment with zoledronic acid (Reclast®) is indicated.

*There is no reauthorization when zoledronic acid (Reclast®) is being given to treat Paget's Disease. After a single treatment of Reclast® in Paget's disease, an extended remission period is observed.

Duration of initial and reauthorization approval: 1 month

Reference

Reclast (zoledronic acid) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation April 2020. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/reclast.pdf

Revision / Date	Implementation Date
Policy created / October 2019	March 2020
Removed POS wording, formatting changes, updated reference / May 2021	January 2022